P1/2

**Date Prepared: July 9, 2010**

SEP 22 2010

## 12 510(k) Summary for Public Disclosure

### 12.1 Submitter's Name/Contact Person

Kris Miller
St. Jude Medical
One St. Jude Medical Drive
St. Paul, MN 55117 USA
Establishment Registration Number: 2184149.

### 12.2 Common or Usual Name

Segmentation Software

### 12.3 Proprietary Name

EnSite Verismo Segmentation Software v.2.0

### 12.4 Classification Name

LLZ, System, Image Processing, Radiological (21 CFR 892.2050) Class II.

### 12.5 Indications for Use

The EnSite Verismo Segmentation Tool (EV1000) is indicated for use in generating 3D models from CT, MR, or rotational angiography DICOM image data. Generated models are intended to be displayed on the EnSite Velocity System.

### 12.6 Device Comparison to the Predicate Device

The EnSite Verismo Segmentation Tool v.2.0 has the same intended use and fundamental scientific technology as the predicate device EnSite Verismo Segmentation Tool v.1.0 (K051840).

All technological characteristics of the EnSite Verismo Segmentation Tool v.2.0 are substantially equivalent to the predicate device EnSite Verismo Segmentation Tool v.1.0 (K051840).

### 12.7 Summary of Non-Clinical Testing

Bench testing was performed to confirm that the changes met design requirements and did not affect the safe or effective use of the product. The following non-clinical bench tests were performed: software verification testing, hazard mitigation testing, code review, user testing, instructions for use (IFU) testing and regression testing.

### 12.8 Summary of Design Control Activities

The development of the EnSite Verismo Segmentation Tool was performed in accordance with St. Jude Medical's Quality System requirements and in compliance with Quality System Regulations design controls requirements documented in 21 CFR 820.30.

### 12.9 Conclusion

The EnSite Verismo Segmentation Tool has the same indications for use, intended use and fundamental scientific technology as the predicate device. All technological characteristics of the EnSite Verismo Segmentation Tool are substantially equivalent to the predicate device.

Where operational and performance differences exist between the proposed device and the predicate device, performance testing demonstrated that these differences do not adversely affect the device's safety and effectiveness.

Therefore, St. Jude Medical considers the EnSite Verismo Segmentation Tool to be substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

St. Jude Medical
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

SEP 22 2010

Re: K101697
Trade/Device Name: EnSite Verismo Segmentation Tool v2.0
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: September 10, 2010
Received: September 13, 2010

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donald J. St.Pierre
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

K101697

# Indications for Use Form

**Device Name**: EnSite Verismo Segmentation Tool v.2.0

SEP 22 2010

## Indications for Use

The EnSite Verismo™ Segmentation Tool (EnSite Verismo) (EV1000) is indicated for use in generating 3D models from CT, MR or rotational angiography DICOM image data. Generated models are intended to be displayed on the EnSite Velocity™ System.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K101697